

Notice of Allowability

Application No.

10/601,862

Examiner

Taylor Victor Oh

Applicant(s)

LOCKE ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/10/05.
2. ☒ The allowed claim(s) is/are 13-20, renumbered as claims 1-8.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>11/29/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>See Continuation Sheet</u> . |

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It is noted that applicants have filed an Amendment after the Final Rejection on 11/10/05; applicants' attorney has addressed the issues of record. The proposed amendment will be entered ; and, it is in a condition for allowance.

Examiner's Amendment and Reasons of Allowance

The Status of Claims

Claims 13-20 are pending.

Claims 13-20 have been allowed.

Claims 1-12 have been canceled.

Amendment to the Specification

It is noted that the Title has been changed from "Polymorphic form A of

4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid

" to "Pharmaceutical compositions of isolated orthorhombic crystalline

4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyric acid

and methods of use."

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1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with an attorney of record, Gilberto M. Villacorta, Ph.D. on 11/29/05 .

I. The application has been amended as follows:

In claim 17, line 1 on page 3 (amendment dated on 11/10/05):

The term "-- a tablet --" before the term "weighing" is replaced with "the tablet".

II. The following is an examiner's statement of reasons for allowance:

- The rejection of Claims 1-3 , 5-9, and 11 under 35 U.S.C. 112, second paragraph, has been withdrawn due to the cancellation of the claims in the amendment.
- The rejection of Claims 1-7 under 35 U.S.C. 112, first paragraph, has been withdrawn due to the cancellation of the claims in the amendment.

- Locke's Declaration has been filed in order to show that each crystalline structure of the two forms, Form A and Form B in Figs 6 and 7 (PXRD analyses of tablets made from the claimed orthorhombic crystals and the undesired monoclinic crystals), which has been retained in the manufacture of the respective tablets.
- The close prior art to the current invention is Ohashi et al (U.S. 4,985, 585).

Ohashi et al discloses the preparation of 4-(6-acetyl-3-(3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy)-2-propylphenoxy)butyric acid crystal compound in the following example:

To a mixture of ethyl 4-[6-acetyl-3-[3-(4-acetyl-3-hydroxy-2-propylphenylthio)propoxy]-2-propylphenoxy]butyrate (2.1 g) in ethanol (10 ml) was added a solution of sodium hydroxide (0.26 g) dissolved into water (10 ml). After heated on hot water bath for 5 minutes, the mixture was cooled by adding ice-water and was made acidic by addition of hydrochloric acid, followed by being extracted with ethyl acetate. The obtained layer was washed with water, dried over sodium sulfate and concentrated. The resultant residue was separated and purified through silica-gel column chromatography (eluting with ethanol:methylene chloride=3:100) to give the title compound (1.3 g, 65.2%) as colorless crystal, mp 79–81° C.

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However, the instant invention differs from the prior art in that the claimed crystalline structure is the orthorhombic crystalline form having twice the solubility of a monoclinic crystalline form at 30⁰ C in aqueous ethanol as well as showing the absence of doublet peaks between 11.5 and 16 (2-Theta scale) in the PXRD figure. Furthermore, Locke's Declaration has shown an unexpected property of retaining the claimed orthorhombic crystalline structure even after the manufacture of the respective tablets as shown in Figs 6 and 7 (PXRD analyses of tablets made from the claimed orthorhombic crystals and the undesired monoclinic crystals).

Thus, the claimed orthorhombic crystalline compound and the prior art compound with respect to the crystalline structure are completely different from each other. In addition, unless all limitations of the claims are met, there is no prior art rejection. See In re Zurko 59 USPQ 2d 1690 (Fed Cir. 1991) and In re Lee, 61 USPQ 1430 (Fed Cir. 1991).

Therefore, the claimed invention would not have been obvious to the person with an ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning the communication after allowance such as sending all post-allowance correspondence should be directed to "Box Issue Fee" or faxed directly to PUBS at 703-305-8755. This will expedite the process of these papers.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mylar ✓ 02
11/30/05

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Continuation of Attachment(s) 9. Other: drawings filed on 2/25/05 are accepted by the examiner.